

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
85-R-0014

CUSTOMER NO.
1076

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

UNIVERSITY OF NEW MEXICO

(b)(2)High, (b)(7)f

OFFICE OF ANIMAL CARE & COMPLIANCE
ALBUQUERQUE, NM 87131
(505) 272-0418

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

See Attached Listing

(b)(2)High, (b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs				130	130
7. Hamsters					
8. Rabbits		115	114	327	556
9. Non-Human Primates					
10. Sheep					
11. Pigs	2		55		55
12. Other Farm Animals					
13. Other Animals					
Opossum			23		23

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF

(b)(6), (b)(7)(c)

ONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

(b)(6), (b)(7)(c)

DATE SIGNED

11-8-07

APHIS FORM
(AUG 91)

VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 19 2007 ✓

CORRECTED COPY - 18 December 2007

Column E Explanation

1. Registration Number: 85-R-0014
2. 457 (130 guinea pigs & 327 rabbits) animals were used in this study
3. In conjunction with the research goals of vaccine or therapy development associated with the rabbit and guinea pig pulmonary infection models, the justification of the un-alleviated pain model is based upon, 21CFR314 section 314.610 #3 [(3) The animal study endpoint is clearly related to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity; and,]. Minimum numbers of animals necessary to accomplish research goals were used. The studies in question utilized rabbits and guinea pigs as preclinical models to assess efficacy of potential vaccine or therapy candidates for protection against disease and death. The incubation period between infection and acute death is several days. Animals are observed multiple times daily by the animal resource facility and the investigator personnel and few animals exhibit clinical signs other than acute death. Rarely animals have been observed with clinical signs just prior to death and on those occasions they died before euthanasia could be administered. Because animals generally appear normal until death, timing administration of analgesics after onset of clinical signs is not feasible and preemptive use of analgesic from the time of infection could result in death of animals that otherwise might survive. Therefore, use of analgesics is contraindicated. If we were able to identify earlier clinical signs that would indicate that death was assured, then we would seek approval from the FDA & sponsors to use these signs as early end-point determinants. However, without such biomarkers, allowing death as an end-point is necessary to determine if the vaccines or other therapies in these trials promote survival. The following is the link to 21CFR314:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=314&showFR=1&subpartNode=21:5.0.1.1.4.9>

DEC 21 2007